

B9
cont.
34. (New) The composition of claim 2 wherein said extract of *Coleus forskohlii* comprises at least 80% forskohlii.--

REMARKS

Appreciation is expressed to the Examiner for including in the scope of examination all of the pending claims, as far as the undersigned understands the situation. For instance, all of the pending claims have received substantive consideration in the claim objections/rejections. However, if this understanding is not correct, the undersigned apologizes and will work with the Examiner to formulate a suitable set of claims.

The Examiner's §112, first paragraph, rejections are based on contentions that the claim should be limited, not only to the presence of *Coleus forskohlii* extract, but to such extracts of a certain nature and containing, evidently, a certain percentage of forskolin. The Examiner's rationale is that the case examples of this application utilized the formulation of example 2, which happened to have an extract of *Coleus forskohlii* and the latter happened to contain about 80% forskolin. However, it is respectfully submitted, that in no way would any of this imply to a skilled worker that the invention presumptively does not work without such an extract and/or without the mentioned specific amount of forskolin. There is absolutely no basis for such a conclusion.

The Examiner is reminded that patent applications are presumptively enabled. *In re Marzocchi*, 169 USPQ 367 (CCPA 1971). Until the Patent and Trademark Office provides "reasons or evidence" to doubt the accuracy of any statement in the specification, there can be no enablement rejection. On this basis alone, all the enablement rejections must be withdrawn. The Examiner provides none of the required reasons or evidence. Rather, unsupported conclusions are given to the effect that, without proof, a skilled worker would doubt that the invention works as stated. However, this puts the cart before the horse. The burden is not on applicants to prove its assertions; rather, it is on the Patent and Trademark Office to create doubt concerning the

assertions. There are no reasons given to doubt the accuracy of the asserted properties of the claimed subject matter. As the Examiner acknowledges, the application provides plentiful evidence that the invention does work as claimed. There is nothing of record to establish that without the *Coleus forskohlii* extract utilized in the examples, the invention would not work. This is mere speculation. This is totally insufficient to support an enablement rejection.

If anything, the Wands factors support enablement, not undermine it.

As already stated, there is nothing of record to indicate that any undue quantity of experimentation would be needed to use any particular formulation within the scope of the claimed subject matter. The specification is replete with direction and guidance as to how to formulate and utilize the claimed subject matter. The application has plentiful working examples. The nature of the invention is not particularly unpredictable, once the specification is taken into account. All of the ingredients themselves are known, although their combinations as claimed are in no way suggested. The art of formulation is also an old one and the skill level is not low. Finally, the Examiner has established no basis to assert that the claims are unduly broad.

Skilled workers readily know and appreciate the definite scopes of the various ingredients recited in the claims such as borage seed oil, *Angelica species* root, *Coleus forskohlii* extract, etc. Just because it is possible to obtain various kinds of extracts within the language employed in the claims does not mean that a skilled worker would have any difficulty formulating the included extracts or in testing them. Nor is the scope of each of the recited ingredients in any way unreasonably broad. These are known ingredients. No undue experimentation is needed to formulate or use the claimed subject matter. There is no unfairness to the public in granting to an inventor a reasonable scope of subject matter claimed based on the disclosure, including its examples.

Nevertheless, in order to expedite prosecution, the nature of the *Coleus* extract is now explicitly recited despite the fact that this was inherent from the content, of e.g., page 4, lines 21-28. In the latter passage, reference is made to several documents for extraction processes with respect to *Coleus forskohlii*. In U.S.P. 4,118,508 (already of record), a list of extracting solvents is given at col. 1, lines 48-55 and preferred solvents at col. 2, lines 37-44. The latter include,

e.g., aromatic hydrocarbons or aliphatic halohydrocarbons, lower alkanols, benzene, toluene, xylene, methylene chloride, chloroform, methanol or ethanol, etc. A skilled worker reading this patent (which is incorporated by reference under clear case law – *In re Hawkins*, 486 F. 2d 579, 179 USPQ 163 (CCPA 1973)) would inherently know that it is lipophilic-type extracts which are disclosed. This has now been added to the claims, along with the fact that extracts are taken from the roots. The latter is clear from the specification (page 4, line 16, as well as U.S.P. 4,118,508). Thus, the term “lipophilic” is used as inherent shorthand which would be necessarily understood by a skilled worker reading the specification and U.S.P. 4,118,508. However, if the Examiner prefers an explicit incorporation by reference by ‘508, she is courteously requested to telephone the undersigned to discuss the matter.

As for the apparent suggestion of the Examiner that the extract be limited to a single specific extract containing 80% forskolin, reference is made to the above-cited case law. Just because a single example is given to illustrate the usefulness of a claimed invention, thus does not mean that all claims must be limited to that given example. Even specifications which contain no examples are enabling. There is no requirement in the law that claims be limited to specific examples. Rather, the law is just the opposite, i.e., claims are not to be so limited. Nor is there any requirement that all aspects of an invention be exemplified. See *In re Angstadt*, 537 F.2d. 498, 190 USPQ 214 (CCPA 1976).

Thus, the claims have been reworded in an effort to comply with the Examiner’s comments and to define a reasonable scope of protection. Applicants presently intend to file a continuation application to seek broader protection.

The prior art rejection is also untenable. The simple facts that ingredients are known and that they can or might be combined are absolutely insufficient to support a rejection. The Examiner must provide motivation for combining the ingredients as claimed. In this case, there is no such motivation.

In Habif et al., it is disclosed that borage seed oil is employed to reduce or eliminate skin irritation induced by hydroxy acids and/or retinoids. The claims make no mention of such irritation or the application of the mentioned ingredients. Thus, whatever motivation Habif et al. provides for adding borage seed oil to any composition is irrelevant to this invention.

The mere fact that Horrobin discloses the use of primrose oil very generically in a wide variety of products such as cosmetic, skin, and hair care products, and pharmaceuticals, is irrelevant to the claimed combinations. This disclosure provides absolutely no motivation to formulate the compositions as claimed, either alone or in view of the Habib disclosure. Just because one could mix together borage seed oil and primrose oil, perhaps in some sort of compositions which also might be used after skin irritation has been induced by hydroxy acids and/or retinoids is irrelevant to the claimed invention. Again, the law clearly requires that the references must provide a reason or suggestion for a skilled worker to put together the components as claimed. There is no such reason or suggestion. It is not sufficient to show that these components exist individually and thus could be put together.

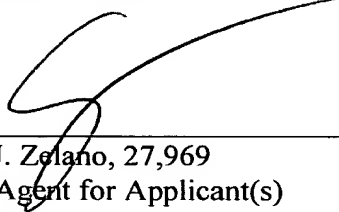
This same conclusion applies fully in view of the Oblong et al. disclosure to which the Examiner refers. The mere fact one could add forskolin to regulate the condition of mammalian keratinous tissue provides no reason to combine this particular ingredient with any of those mentioned in any of the other references for the purposes of the other references or this invention. All these references appear to be doing different things for different purposes. To establish obviousness, one cannot simply say that any ingredient ever known for any skin condition is obvious to combine with every other ingredient ever known for any other skin condition.

The foregoing comments remain applicable even when considering the fourth disclosure, i.e., that of Kuniyoshi, relating to use of vinpocetine allegedly for a skin improving effect. Again, the same is true even when further considering the disclosure of Tian, allegedly that Angelica root has been used in skin creams to beautify and heal dry skin.

Overall, the mere possibility of combining these ingredients known for disparate uses in no way is sufficient to render the claimed subject matter obvious. The Examiner has provided no motivation for modifying the prior art in the way required to arrive at the claimed subject matter. See, for example, *In re Jones*, 958 F. 2d. 347, 21 USPQ 2d 1941 (Fed. Circuit 1992).

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,



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Attorney Docket No.: UROMED-1

Date: January 27, 2003

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Name: JANICE ADLER
Signature: JANICE ADLER
Date: JANUARY 27, 2003

VERSION WITH MARKINGS TO SHOW CHANGES MADE

Please amend the claims as follows:

2. (Amended) A The topical composition of claim 1, further comprising:
c) an effective amount of lipophilic extract from Coleus forskohlii ~~extraet~~ root.
3. (Twice Amended) A The topical composition of claim 28, further comprising:
c) an effective amount of vinpocetine.
5. (Twice Amended) A The topical composition of claim 28, wherein
a d borage seed oil is 10-99% w/w of said composition,
b e Angelica pubescens root ~~extraet~~ is 0.001-99% w/w of said composition,
and
e f Coleus forskohlii extract is 0.001-8% w/w of said composition.
13. (Twice Amended) A The topical composition of claim 28, further comprising a pharmaceutically acceptable topical excipient.
14. (Amended) A The topical composition of claim 13, wherein said excipient is one or more of: magnesium and its salts, ferulic acid, capric/caprylic triglyceride, silica, vitamin E, vitamin E acetate or salts thereof, ascorbyl palmitate or salts thereof, saccharin, fragrances, and flavors.
15. (Amended) A The topical composition of claim 13, further comprising 2-10 wt% deionized distilled water, .5-5 wt% sorbitan monooleate, 0.5-5 wt% lecithin and 0.25-2 wt% of flavor and/or fragrance enhancers.

16. (Amended) A method of facilitating female sexual arousal, female sexual response or heightened female genital sensation, comprising administering an effective amount of a composition of claim 1 2.

17. (Twice Amended) A method of treating female sexual arousal disorder, female orgasmic disorder, or female sexual pain disorder comprising administering an effective amount of a composition of claim 1 2.

18. (Amended) A method of treating female sexual dysfunction, comprising administering an effective amount of a composition of claim 1 2.

26. (Amended) A The topical composition of claim 1 wherein said Angelica species is archangelica, sinensis, sylvestris, officinalis, acutiloba, or pubescens, or archangel, European angelica or garden angelica.

27. (Amended) A The topical composition of claim 1 wherein said Angelica root is Angelica pubescens.

28. (Amended) A The topical composition of claim 27 further comprising:
(c) an effective amount of lipophilic extract from Coleus forskohlii ~~extract~~ root.

29. (Amended) A The topical composition of claim 2, further comprising primrose oil.

30. (Amended) A The topical composition of claim 28, further comprising primrose oil.